



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,256	12/12/2003	Stephen M. Strittmatter	2159.0420002/EJH/SAC	9794

53644 7590 05/16/2006

STERNE, KESSLER, GOLDSTEIN & FOX, P.L.L.C.
1100 NEW YORK AVE., N.W.
WASHINGTON, DC 20005

EXAMINER

WANG, CHANG YU

ART UNIT	PAPER NUMBER
----------	--------------

1649

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No.	Applicant(s)	
	10/735,256	STRITTMATTER ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 May 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: 34 and 47.
Claim(s) rejected: 31-33, 35-46 and 48-66.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.


Continuation of 11, does NOT place the application in condition for allowance because:

The rejection of claims 31-33, 35-46 and 48-66 under 35 U.S.C. §112, first paragraph, because the specification would not be enabling for polynucleotides encoding a polypeptides at least 80-95% identical to a polypeptide comprising amino acids 1-310 of SEQ ID NO 2 is maintained. The rejection is maintained for the reasons set forth in the previous office action and reillustrate herein. Applicant argues that the specification provides enough teachings and knowledge for an ordinary skill in the art to practice the full scope of the claimed invention without more than routine experimentation. Applicant argues that a skilled artisan does not need to be able to predict the structural and functional consequence of mutations/amino acid changes to practice the claimed invention. Applicant further argues that the specification teaches how to obtain DNA molecules that encode a polypeptide comprising amino acids 1-310 or 31-310 of SEQ ID NO:2 or at least 80%-95% identical to amino acids 1-310 or 31-310 of SEQ ID NO: 2 and also a method to test whether these DNA molecules have the ability of modulate inhibition of axonal elongation. Applicant further states that if the DNA molecules have no ability of modulating inhibition of axonal elongation, the skilled artisan can discard the non-active molecules. Applicant's arguments have been fully considered. However, they are not found persuasive. The claims are directed to a polynucleotide encoding a polypeptide at least 80%-95% identical to a polypeptide comprising amino acids 1-310 or 31-310 of SEQ ID NO:2 wherein the polypeptide modulates inhibition of axonal elongation. The word "comprising" is open language. A nucleic acid sequence encoding a polypeptide at least 80-95% identical to a polypeptide comprising amino acids 1-310 or 31-310 of SEQ ID NO:2 includes amino acid sequences other than amino acid 1-310 or 31-310 of SEQ ID NO:2; i.e. sequences not within the region of 1-310 or 31-310 of SEQ ID NO:2. Applicant has not provided the structural/functional limitations of these unknown sequences other than SEQ ID NO:2. Therefore, whether these unknown sequences can affect the activity of inhibiting axonal elongation of the claimed invention is unknown, indicating that undue experimentation is required. In addition, the guidance of specification in the claimed invention should be in light of how to make and use the invention rather than testing/screening for DNA molecules to see whether they have the claimed activity and discarding the nonactive molecules, suggesting that too much uncertainty for a skilled in the art to practice the invention. Therefore, whether a nucleic acid sequence encoding a polypeptide at least 80%-95% identical to a polypeptide comprising amino acids 1-310 or 31-310 of SEQ ID NO:2 can inhibit axonal elongation is unpredictable, indicating that undue experimentation is required to practice the claimed invention commensurate in the scope with these claims.

The rejection of claims 31-33, 35-46 and 48-66 under 35 U.S.C. § 112, first paragraph, as failing to meet the written description is maintained. The rejection is maintained for the reasons set forth in the previous office action and reillustrate herein. Applicant argues that the Example 14 of the USPTO's Written Description Synopsis is very similar to the situation of the claimed invention. Applicant argues that all species of the polynucleotides encompassed by Applicant must encode polypeptides that have at least 80%-95% homology to amino acids 1-310 or 31-310 of SEQ ID NO:2 and these polypeptides must modulate inhibition of axonal elongation. Applicant further argues that the specification does show actual reduction of the practice of SEQ ID NO:2 and one of ordinary skill in the art could easily to make and test polynucleotides encoding polypeptides at least 80%-95% identical to amino acids 1-310 or 31-310 of SEQ ID NO:2 wherein the polypeptides modulate inhibition of axonal elongation. In addition, Applicant argues that the specification teaches to identify other protein having the required activity. Applicant's arguments have been fully considered. However, they are not found persuasive. The claims are directed to a polynucleotide encoding a polypeptide at least 80%-95% identical to a polypeptide comprising amino acids 1-310 or 31-310 of SEQ ID NO:2 wherein the polypeptide modulates inhibition of axonal elongation. Applicant may in possession polynucleotides encoding polypeptides that have at least 80-95% identity to amino acids 1-310 or 31-310 of SEQ ID NO:2. However, Applicant is not in possession of all polynucleotides encoding all polypeptides at least 80%-95% identical to a polypeptide comprising amino acids 1-310 or 31-310 of SEQ ID NO:2. Applicant fails to teach what other common structures/characteristics are required for the sequences other than amino acids 1-310 or 31-310 of SEQ ID NO:2. The Example 14 in USPTO's Written Description Synopsis indicates that "all variants must possess the specified catalytic activity and must have at least 95% identity to SEQ ID NO:3" as quoted by Applicant. Applicant fails to specify/describe the functional limitations of the amino acid sequences other than SEQ ID NO:2. In addition, the polynucleotides encoding polypeptides at least 80%-95% identical to a polypeptide comprising amino acids 1-310 or 31-310 of SEQ ID NO:2 are much broader than the polynucleotides encoding polypeptides at least 80-95% identical to amino acids 1-310 or 31-310 of SEQ ID NO:2 or a polypeptide consisting of amino acids 1-310 or 31-310 of SEQ ID NO:2, which may not be possessed by Applicant and may not have the activity of inhibiting axonal elongation.

Claim Objections

Claims 34 and 47 are allowable however they are objected to as being dependent from the rejected claims. Applicant is required to amend the claim(s) to place the claim(s) in proper form, or rewrite the claim(s) in independent form.


JANET L. ANDRES
SUPERVISOR, PATENT EXAMINER